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NOTICE OF ALLOWANCE AND FEE(S) DUE

20462 7590 10/01/2010

GlaxoSmithKline
GLOBAL PATENTS -US, UW2220
P. O. BOX 1539
KING OF PRUSSIA, PA 19406-0939

EXAMINER	
ROGERS, JAMES WILLIAM	
ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 10/01/2010

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/470,438	01/06/2004	Stephen Mark McAllister	P51223	8426

TITLE OF INVENTION: PHARMACEUTICAL FORMULATION

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	$1510	$300	$0	$1810	01/03/2011

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PTOL-85 (Rev. 08/07) Approved for use through 08/31/2010.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

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Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/470,438	01/06/2004	Stephen Mark McAllister	P51223	8426

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nonprovisional	NO	$1510	$300	$0	$1810	01/03/2011

EXAMINER	ART UNIT	CLASS-SUBCLASS
ROGERS, JAMES WILLIAM	1618	424-451000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,

(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____

2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. The following fee(s) are submitted:

❑ Issue Fee

❑ Publication Fee (No small entity discount permitted)

❑ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**

❑ A check is enclosed.

❑ Payment by credit card. Form PTO-2038 is attached.

❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)

❑ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

❑ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

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EXAMINER	
ROGERS, JAMES WILLIAM	
ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 10/01/2010

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Notice of Allowability	Application No.	Applicant(s)	
	10/470,438	MCALLISTER ET AL.	
	Examiner	Art Unit	
	JAMES W. ROGERS	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *Applicant Arguments/Remarks Made in an Amendment filed 05/12/2010*.

2. ☒ The allowed claim(s) is/are *56-70*.

3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☒ All b) ☐ Some* c) ☐ None of the:
      1. ☒ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 06/30/2010 and 07/16/2010
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Dara L. Dinner on 7/26/2010.

The application has been amended as follows:

Specification

Specification on page 26 line 30 has been amended as follows: The new sentence "The surfactant(s) can also be present in an amount less than 5% w/w." has been added after the recitation "surfactant(s)." in line 30 of page 26.

This amendment to the specification finds support in the original claim set, specifically claim 3.

Claims

Claims 42,44-54,71-94 and 96-109 are cancelled.

Claim 56 has been amended as follows:

56. A process for making a pharmaceutical dosage form comprising the steps of:

a) introducing

a copolymer of methyl acrylate, methyl methacrylate and methacrylic acid, with a ratio of free carboxyl groups to esters groups of 1:10, and an average molecular weight of approximately 220,000, present in an amount of about 20 to 90% w/w, and

an excipient composition comprising:

a lubricant present in an amount of about 10 to about 25% w/w; at least one dissolution-modifying excipient selected from the group consisting of a swellable solid, disintegrant, non-reducing sugar, water soluble filler, wicking agent, and an inorganic salt present in an amount of about 2.5 to about 70% w/w; and

a surfactant present in an amount of less than 5% w/w, the surfactant selected from a block copolymer of ethylene oxide and propylene oxide, lecithin, sodium dioctyl sulfosuccinate, sodium dodecyl sulphate, polyoxyl 40 hydrogenated castor oil, polyoxyethylene sorbitan fatty acid ester, sorbitan fatty acid ester, polyethylene glycol, d-alpha-tocopheryl polyethylene glycol 1000 succinate, or a sucrose fatty acid ester, or combinations and mixtures thereof; and

optionally a plasticizer present in an amount of 0 to 10% w/w, optionally a processing agent present in an amount of 0 to about 10% w/w;

simultaneously, and at substantially the same location, into an elongated hot melt extruder;

b) mixing said copolymer and said excipient composition in the hot melt extruder to form a homogeneous composition, and ejecting the homogeneous composition in the form of a strand from the hot melt extruder though a die at a location remote from said same location at which the copolymer and said excipient composition are introduced;

c) cutting the strand into pellets;

d) introducing said pellets into an injection molder and forming capsule shells by injection molding.

Claim 58 has been amended as follows:

58. The process according to Claim 56, in which the surfactant is selected from sodium dodecyl sulphate or a block copolymer of ethylene oxide and propylene oxide.

Claim 65 line 2 has been amended as follows, the word “out” has been added between the words “carried” and “using”.

Claim 66 line 2 has been amended as follows, the word “out” has been added between the words “carried” and “using”.

Claim 67 line 2 has been amended as follows, the word “out” has been added between the words “carried” and “using”.

Claim 68 line 2 has been amended as follows, the word :”compartments” has been deleted and the word “shells” has been added to replace the word “compartments”.

Claim 69 line 1 has been amended as follows, the word ”compartments” has been deleted and the word “shells” has been added to replace the word “compartments”.

Claim 69 line 3 has been amended as follows, the word ”components” has been deleted and the word “shells” has been added to replace the word “components”.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES W. ROGERS whose telephone number is (571)272-7838. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L7	536	(capsule near (shell or wall)).CLM.	US-PGPUB; USOCR	ADJ	ON	2010/07/28 11:13
L8	783	(INJECTION AND EXTRUDED).CLM.	US-PGPUB; USOCR	ADJ	ON	2010/07/28 11:13
L9	1087	(($5methyl near3 acrylate) and ($5methyl near3 methacrylate) and ($5methacrylic near3 acid)).clm.	US-PGPUB; USOCR	ADJ	ON	2010/07/28 11:13
L10	1	7 and 9	US-PGPUB; USOCR	ADJ	ON	2010/07/28 11:14

7/28/2010 11:15:24 AM
C:\Documents and Settings\jrogers2\My Documents\EAST\Workspaces\10470438.wsp

Search Notes

Application/Control No.	Applicant(s)/Patent under Reexamination
10/470,438	MCALLISTER ET AL.
Examiner	**Art Unit**
JAMES W. ROGERS	1618

SEARCHED			
Class	Subclass	Date	Examiner

INTERFERENCE SEARCHED			
Class	Subclass	Date	Examiner
424	**451**	**7/28/2010**	**JR**

SEARCH NOTES (INCLUDING SEARCH STRATEGY)		
	DATE	EXMR
Considered IDS's newly submitted	7/28/2010	JR
Patentability conf. with Mike Hartley, SPE and Jake Vu, pri. examiner	7/27/2010	JR

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/060,849	01/30/2002	Stephen Mark McAllister	P51223	9605

7590 06/30/2010

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EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
06/30/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/060,849	**Applicant(s)** MCALLISTER ET AL.	
	Examiner S. TRAN	**Art Unit** 1615	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 28 June 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on *28 June 2010*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1-33,35,38-40,71-97,112-132 and 134-136*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/S. TRAN/
Primary Examiner, Art Unit 1615

Continuation of 3. NOTE: newly submitted amendment requires reconsideration and search.

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TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
12/28/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/060,849	MCALLISTER ET AL.	
	Examiner	Art Unit	
	S. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 September 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33,35,38-40,71-97,112-132 and 134-136* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-33,35,38-40,71-97,112-132 and 134-136* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The 112 rejections of record have been withdrawn in view of applicant's Remarks filed 09/04/09, at pages 23-27.

Claim Rejections - 35 USC § 103

Claims 1, 2, 7-16, 20-22, 39, 40, 73, 74, 81-74, 87-90, 92-95, 112 and 113 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petereit et al. US 20020160042, in view of Lehmann et al. US 5,705,189.

Petereit teaches an injection molding composition comprising: a) 45-100% methacrylate copolymer; b) 0.1-3% lubricant; c) 0-50% drier; d) 0-30% plasticizer; e) 0-100% additives or auxiliaries; f) active agent; and g) 0-20% of another polymer or copolymer (paragraphs 0019-0027). Methacrylate copolymer includes 50-70% methyl acrylate, 10-30% methyl methacrylate, and 5-15% methacrylic acid (a 7:3:1 ratio if converted) (paragraph 0038). Plasticizer includes castor oil, sorbitan ester, and polyethylene glycol (paragraphs 0050-0051). Other polymer or copolymer includes polyvinyl pyrrolidone (paragraphs 0078-0080). Petereit further teaches the shape of the molding includes capsule, part of a capsule such as half or a capsule (paragraph 0095). Petereit also teaches the wall thickness of the obtained capsule is of 0.6 mm (paragraph 0101).

Petereit does not explicitly teach the claimed percent amount of lubricant from 5% to about 30%. However, differences in concentration will not support the

patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). In the present case, it would have been obvious to one of ordinary skill in the art to, by routine experimentation select a lubricant amount that falls within the claimed range with the expectation of lat least similar result. This is because Petereit teaches the use of the same lubricant, such as stearyl alcohol, for the same purpose, namely, as a mold releasing agent (paragraphs 0041-0044). Further, the use of lubricant as a mold releasing agent in the claimed amount is known in the art. See for example the teaching of Lehmann at column 3, lines 65-67; and example 1. Lehmann teaches the use of 6% of the mold releasing agent, based on the weight of the polymer. Accordingly, it would have been obvious to one of ordinary skill in the art to modify the molding composition of Petereit using lubricant in the claimed amount in view of the teachings of Lehmann.

Petereit further does not teach that the capsule shell composition is substantially pH-independent. It is noted that nowhere in Petereit does the teaching of pH-dependent disclose. Accordingly, the burden is shifted to applicant to show that the capsule composition of Petereit is substantially pH-dependent. This is because Petereit teaches the use of the same polymers and in the same amounts to prepare a composition for the same purpose desired by the applicant, namely, a capsule shell composition useful in pharmaceutical art.

Claims 3-6, 18 and 75-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petereit et al. US 20020160042, in view of Bolles US 3,779,942 and Zentner US 4,795,644.

Petereit is relied upon for the reason stated above. Petereit does not expressly teach the use of surfactant.

Bolles teaches a capsule shell composition comprising well known polymer such hydroxypropyl cellulose, and surfactant such as sodium dioctyl sulfosuccinate in an amount of from about 0.001-10% (abstract; and column 2, lines 20-59). Thus, it would have been obvious to one of ordinary skill in the art to optimize the capsule shell composition of Petereit to include surfactant to obtain the claimed invention. This is because Bolles teaches that the addition of surfactant to improve capsule shell storage stability, uniformity and strength (abstract; and column 2, lines 2-8).

Bolles does not teach the claimed surfactant such as sodium dodecyl sulfate. Zentner teaches useful surfactant for wall forming composition includes sodium dodecyl sulfate, and sodium dioctyl sulfosuccinate (column 13, lines 53 through column 14, lines 1-22). Thus, it would have been obvious to one of ordinary skill in the art to, by routine experimentation select sodium dodecyl sulfate as a surfactant, because Zentner teaches the equivalency between sodium dodecyl sulfate, and sodium dioctyl sulfosuccinate, and because Zentner teaches the use of sodium dodecyl sulfate in wall forming composition is known in the art.

Claims 1-33, 35, 38-40, 71-97, 112-132 and 134-136 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petereit et al. US 20020160042, in view of Lehmann et al. US 5,705,189, Hatano et al. US 6,309,666, and Klug et al. US 3,314,809.

Petereit is relied upon for the reasons stated above. Petereit further does not teach the inclusion of additives such as lactose and mannitol.

Hatano teaches coated capsule compositions comprising a hard outer shell (abstract). The compositions may be formulated for quick release at a desired location in the gastrointestinal tract (column 2, lines 49-62). Suitable materials for the outer shell include methacrylate co-polymers and acrylic co-polymers (column 5, line 42 to column 6, line 23). Each of the components of the capsule, including the hard outer shell, may include various excipients, including binders, disintegrants, lubricants, aggregation-preventing agents, plasticizer, and a surfactant. Excipients include mannitol, lactose and starch. Binders include ethylcellulose, polyvinylpyrrolidone, HPMC, and polyethylene glycol (column 12, lines 1-11). Disintegrants include polyvinylpyrrolidone and hydroxypropylcellulose (column 12, lines 12-17). Lubricants and aggregation-preventing agents include talc, magnesium stearate, and colloidal silicon dioxide. Plasticizers include diethyl phthalate, dibutyl phthalate, and polyethylene glycol. Surfactants include polyoxyethylene sorbitan monooleate, poiyoxyethylene hydrogenated castor oil, and sodium dodecyl sulfate (column 11, line 52 to column 12, line 65). Such additives may be added in any amount within the scope of the knowledge of one of ordinary skill in the art (column 13, lines 3-5). Thus, it would

have been obvious to one of ordinary skill in the art to optimize the capsule shell composition of Petereit to include the excipients in view of the teachings of Hatano. This is because Hatano teaches the use of well known excipients in pharmaceutical art in capsule shell composition, and because Petereit teaches the desirability of using excipients or other auxiliaries known in the art.

It is noted that applicant argues that Petereit teaches the use of HPC in a long list, and there is no motivation to select HPC. However, Klug teaches a capsule shell composition comprising HPC (columns 1-2). Thus, the skilled artisan would have been motivated to select HPC as other polymer for the capsule shell composition of Petereit in view of the teachings of Klug, because Klug teaches that HPC is the stable thermoplastic material for making excellent articles such as capsule shell (column 4, lines 56 through column 5, lines 1-15).

Response to Arguments

Applicant's arguments filed 09/04/09 have been fully considered but they are not persuasive.

Applicant argues that the formulation of the copolymer blend used in the Petereit process does not teach a combination of two (2) dissolution modifying agents as required by claim 1 herein. One of the dissolution modifying excipients for use in the instant invention is a swellable solid. In Petereit, there is no express statement of swellable solids, but use of a second copolymer. The copolymer is an optional excipient in Petereit's blend, being present from 0-20% w/w. Consequently, the resulting blend

does NOT require such an excipient to being present. The list of polymers suitable for use in the Petereit formulation in disclosed in paragraph 0080 shown below. This paragraph provides for a long list of many polymers not claimed or disclosed for use within the context of Applicants invention as a dissolution modifying excipient. Therefore, even if a copolymer is present one would not necessarily be directed to pick and choose as an excipient that one which Applicant describes as a dissolution modifying excipient.

However, in response to applicant's argument that "*[o]ne of the dissolution modifying excipients for use in the instant invention is a swellable solid. In Petereit, there is no express statement of swellable solids, but use of a second copolymer*", it is noted that the "swellable solid" is recited in a Markush group. Thus, at least independent claim 1 does not necessarily require that the "swellable solid" as one of the dissolution modifying excipient in view of the Markush language. Further, in response to applicant's argument that "*the copolymer is an optional excipient in Petereit's blend, being present from 0-20% w/w. Consequently, the resulting blend does NOT require such an excipient to being present*", the Examiner notes that although the excipient is not required, it can be present. The phrase "optional" clearly indicates that it could be present. Moreover the amount of up to 20% indicates that the excipient does present in the blend.

Moreover, in response to applicant's argument that "*the list of polymers suitable for use in the Petereit formulation in disclosed in paragraph 0080 shown below. This paragraph provides for a long list of many polymers not claimed or disclosed for use*

within the context of Applicants invention as a dissolution modifying excipient", it is noted that the list of dissolution modifying excipients recited in claim 1 is broad. See for example "swellable solid" or "water soluble filler".

Applicant argues that in the present invention:

1) the capsule shell and/or linker is meant to break apart at a particular time, and release the contents of the shell/linker to the GI tract at that time, all at once, not over a period of time to provide a controlled constant rate of release;

2) the 4135F polymeric formulations provide for a capsule shell that has a more delayed, or prolonged time period to release the capsule contents into the GI tract; than a gelatin capsule which is of the immediate release;

3) when a multicomponent dosage form of the present invention, is assembled it is possible to have a shell subunit that disperses the contents as an immediate release, and be linked to a second, or third, etc. shell subunit that disperses the contents as pulsitile releases, much later down the GI tract; and

4) prior to the disclosure by Applicants it was not believed possible to prepare a pH-independent **capsule shell or linker itself** using the copolymers as recited in the presently amended claims.

However, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the captured features (1) to (4) above) are not recited at least in the rejected independent claim(s). Although the claims are interpreted in light of the

specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

To place the application in condition for allowance, it is suggested to: 1) clarify the dissolution modifying excipients to include specific combination; and 2) incorporate the above captured features 1-4 into all independent claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 8:30 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. Tran/
Primary Examiner, Art Unit 1615